DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

93671

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

VIA FEDERAL EXPRESS
VIA FACSIMILE

NOV - 8 2002

WARNING LETTER

Mr. Richard J. Sullivan
Chairman/Chief Executive Officer
Applied Digital Solutions, Inc.
400 Royal Palm Way, Suite 410
Palm Beach, Florida 33480

Re: VeriChip

Dear Mr. Sullivan:

This responds to a letter dated November 5, 2002, from Scott R. Silverman to Daniel E. Troy regarding the implementation by Applied Digital Solutions, Inc. (ADS) of a "marketing plan" that the company has begun for its product known as the VeriChip, a microminiature transponder that is encapsulated in medical grade glass that may be inserted by hypodermic needle under the skin of the upper arm in humans.

As the Food and Drug Administration (FDA) has repeatedly advised ADS and its counsel, most recently by letter from the Office of the Chief Counsel dated October 21, 2002, the VeriChip is a medical device if it is marketed with claims of medical utility (e.g., to provide access to medical history or other information to assist medical personnel in diagnosing or treating an injury, illness, or condition). Although we had understood from ADS's repeated assurances that the company had no immediate intention of marketing the VeriChip for medical applications without first consulting with FDA's Center for Devices and Radiological Health (CDRH) regarding applicable legal and regulatory requirements, we now see that ADS has resumed its marketing of the VeriChip for precisely these applications. Indeed, the "marketing plan" described in Mr. Silverman's letter appears to hinge precisely on the very claims of medical utility that, as we have repeatedly advised ADS, make the VeriChip a medical device under Section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act or Act), 21 U.S.C. § 321(h). ADS's conduct flagrantly disregards FDA's prior comprehensive advice.

As a medical device, the VeriChip is subject to many legal and regulatory requirements, one of which is a requirement that products receive clearance or approval from FDA prior to marketing. You have not obtained such clearance or approval. Consequently, the VeriChip is adulterated under Section 501(f)(1)(B) of the FD&C Act or misbranded under Section 502(o) of that Act, 21 U.S.C. §§ 351(f)(1)(B) & 352(o). The VeriChip and ADS could also be in violation of other provisions of the FD&C Act. It is your responsibility to ensure that the VeriChip complies with all applicable requirements of the Act.

If ADS continues to market the VeriChip for medical applications, FDA is entitled to initiate enforcement action without further informal notice. Such action could include, for example, seizure of product inventory, injunctive relief preventing ADS from further marketing the VeriChip, and civil money penalties. Violations of the FD&C Act are also punishable by criminal penalties.

The FDA expects ADS to correct these violations immediately. Your corrective actions should include steps to correct misleading information about the VeriChip currently in the marketplace and measures to prevent similar violations in the future. Please notify us in writing of the specific corrective actions you have taken. We expect to receive your response within 15 working days of the date of this letter.

Your response should be sent to Philip J. Frappaolo, Acting Director, Office of Compliance, (HFZ-300), 2094 Gaither Road, Rockville, Maryland 20850, with a copy to Daniel E. Troy, Chief Counsel, Food and Drug Administration, 5600 Fishers Lane (GCF-1), Rockville, Maryland 20857.

Sincerely yours,

Kimber Richter for

Philip J. Frappaolo
Acting Director
Office of Compliance
Center for Devices and
Radiological Health